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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,233

06/26/2006

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

10/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,233	<b>Applicant(s)</b> KOYANO ET AL.	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-17 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

Claims 1-17, are pending in this application.

## **DETAILED ACTION**

### ***Election/Restriction***

Claims 1-17 are drawn to more than one inventive concept (as defined by PCT Rule 13) and, accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that "special technical features" mean those technical features which, as a whole, define a contribution over the prior art (novelty/unobviousness).

I. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only one heteroatom, and it is a 5-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

II. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only one heteroatom, and it is a 6-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

III. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only two heteroatoms, and it is a 5-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

IV. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only two heteroatoms, and it is a 6-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

V. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only three heteroatoms, and it is a 5-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

VI. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only three heteroatoms, and it is a 6-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

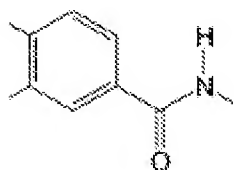
VII. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only four heteroatoms, and it is a 5-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

VIII. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only four heteroatoms, and it is a 6-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

IX. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has only five heteroatoms, and it is a 6-atom ring, and L is one (only) of the formulae in claim 1, classifiable in several non-heterocyclic classes and numerous subclasses.

X. Claim 13-17, drawn to various methods of using compound of formula I, classifiable in several non-heterocyclic classes and numerous subclasses.

1. In the instant inventions, the only structural element shared by groups I-X is



. However, the structure is not novel. See WO 97/03967. Therefore, under PCT Rules 13.1 and 13.2, the structure does not constitute a corresponding special technical feature among the groups.

2. Each of the different methods of use of the inventions set forth in Group X is unrelated to the others. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology for treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different

methods of use of the compounds are unrelated because the patient populations being treated are different.

If applicant elects invention of group X or in a rejoinder thereof applicant must elect a specific disease and group X would be examined commensurate in scope therewith. Applicant must also one of groups I-IX and group X would be examined commensurate in scope therewith.

In electing any of groups I-X, applicant must elect the specific heteroatom(s) in ring A1-Q1-Q2, and specify which of A1-A5, Q1 or Q2 corresponds to each elected heteroatom (only one heteroatom for each position at A1-A5, Q1, or Q2).

3. In an election of any of Groups I-X, an election of a single compound (or set of compounds) is further required including an exact definition of each substitution on the base molecule (Formula I), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl, and each subsequent variable position.

In the instant case, Applicant must elect one representative for each of A1-A5, Q1-Q2, X1-X5, L, Y and Z in formula II, and the point of attachment of each elected substituent must be specified. The elected substituents must be specific not generic so as to define a species, and the species must be disclosed in the specification. Part of the species corresponding to each substituent in formula II must be identified.

All compounds falling outside the class(es) and subclass(es) of the selected compounds and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

October 23, 2008

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